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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Claude Mialhe

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YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER

COLELLO, ERIN L

ART UNIT

PAPER NUMBER

4148

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,148	Applicant(s) MIALHE, CLAUDE	
	Examiner ERIN COLELLO	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “removable guide (7)” and the “removable sheath (8)”, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the

description: "Passage (3)". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 uses the term "it" which is vague and indefinite because it fails to specifically define the parameter that is comprised of the obturation elements.

Correction is needed.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 11 recites the limitation "attachment systems" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2,4, 6-8 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by **De la Torre et al (5,957,913)**.

Regarding claim 1, De la Torre discloses an occlusive device for medical or surgical use, comprising a hollow cylindrical element (Figure 32, (392); Column 15, Lines 21-22) that can be twisted according to its axis to create a striction zone (Column 16, Lines 49-53), characterized in that it comprises two obturation elements (Figure 32, (410, 382)) integral to the inner wall of the cylindrical element (Column 15, Lines 40-42), leaving a passage (Figure 32 see below; Column 16, Lines 46-49) and arranged to press against each other to block the passage when the cylindrical element is twisted (Column 16, Lines 49-53).

Regarding claim 2, De la Torre discloses that the two obturation elements (Figure 32, (410,382)) are integral to two distinct areas of the length of the cylindrical element (Figure 32, (392); Column 15, Lines 40-42).

Regarding claim 4, De la Torre discloses that the two obturation elements (Figure 32 see below, (410, 382)) integral to two diametrically opposed areas of the wall of the cylindrical element (Figure 32, (392); Column 15, Lines 31-32, 40-42).

Regarding claim 6, De la Torre discloses that there are two end parts (Figure 32, (396,428)), surrounding the cylindrical element (Figure 32, (392)) and whose angular position determines the torsion of said cylindrical element (Column 15, Lines 39-43; Column 16, Lines 4-6, 50-53).

Regarding claim 7, De la Torre discloses that the cylindrical element has a circular cross section (Figure 32, (392), where it is well known that the cross-section of a cylinder is a circle).

Regarding claim 8, De la Torre discloses that the obturation elements (Figure 32 see below, (410,382)) are applied one against each other by means of one of their lateral surfaces (Column 16, Lines 50-53, where inlet is closed because each obturation element is applied against each other)

Regarding claim 17, De la Torre discloses a valve (Column 16, Lines 61-64) for surgical or medical instrument, comprising a closeable passage (Column 16, Lines 50-54, where the inlet is the closeable passage).

Regarding claim 18, De la Torre discloses that the cylindrical element (Figure 30, (392)) can be twisted by means of two rings (Figure 30, (410, 408)), each of which is integral to one end of the cylindrical element (Column 16, Lines 50-53).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3,9- 12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **De la Torre et al (5,957,913)**.

Regarding claim 3, De la Torre discloses obturation elements (Figure 32, (410,382)) but fails to disclose obturation elements with a crescent-shaped cross section.

However, the limitation of the “obturation elements with a crescent-shaped cross section” presents no novel or unexpected results over the obturation elements used in the references. Use of such obturation elements in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill of the art.

Regarding claim 9, De la Torre discloses an occlusion device and states that the invention can be constructed in various different sizes (Column 4, Lines 35-37). De la Torre fails to specify that the invention is a vascular occlusion device.

However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed

apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987).

Regarding claim 10, De la Torre discloses two end parts (Figure 32, (396, 428)), surrounding the cylindrical element (Figure 32, (392)) and whose relative angular position determines the torsion of said cylindrical element (Column 15, Lines 39-43; Column 16, Lines 4-6, 50-53), said end parts possessing means of attachment to the wall of a vessel (Column 17, Lines 27-31). De la Torre fails to disclose that both end parts have means of attachment to the wall of the vessel.

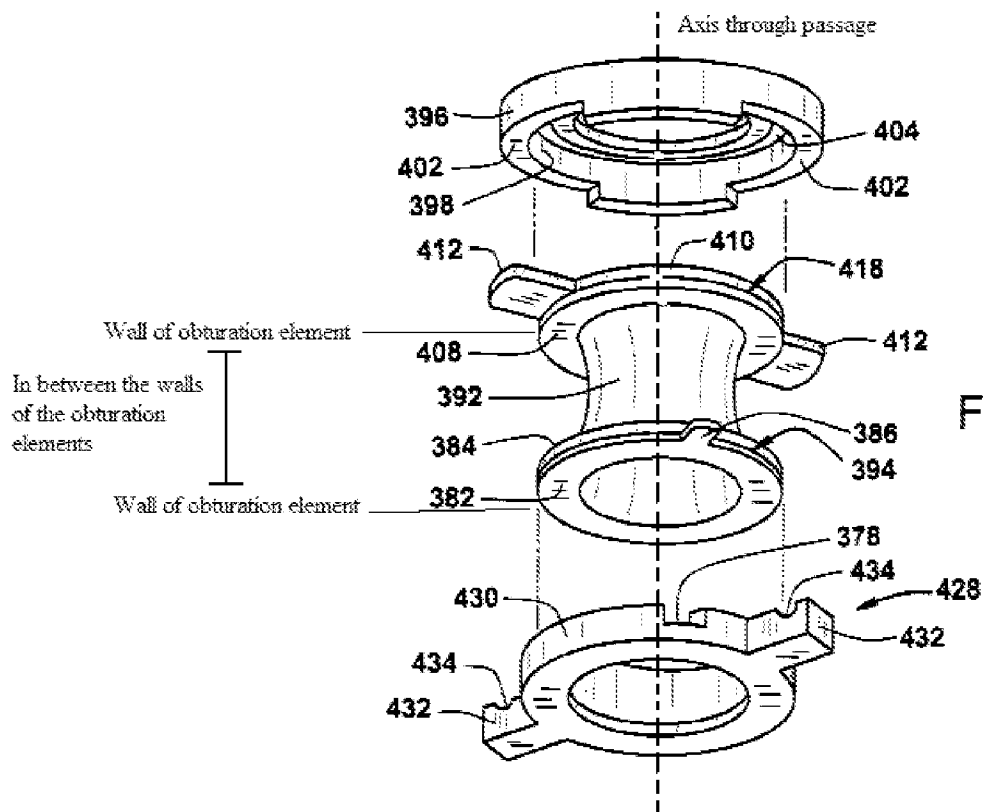
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the end part (396) with the end part (428) which possess means of attachment to the wall of the vessel since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Regarding claim 11, De la Torre discloses that the attachment systems are expanding elements (Column 17, Lines 27-31, where the sutures are able to expand in size when they are loosened).

Regarding claim 12, De la Torre discloses a seal (Figure 32, (428)) on the outer surface of at least one of the expanding elements (Column 17, Lines 27-31, where the suture is the expanding element), said seal being appropriate for application to the wall of a vessel, (Figure 32, (428) where the seal is formed between the vessel wall and the device by suturing).

Regarding claim 14, De la Torre discloses a removable guide (Column 16, Line 54, where a removable guide is the object inserted) positioned according to the axis of the cylindrical element (Figure 32, (392)) and crossing the passage (Column 16, Line 54-55, where the inlet refers to the passage and the axis of the cylindrical element runs parallel through the inlet)

Regarding claim 15, De la Torre discloses a removable sheath (Figure 32, where sheath is the outside surface of the cylindrical member (392)) inserted between the wall of the obturation elements (Figure 32, (410, 382) see below) and the external wall of the guide (Column 16, Line 54, where a removable guide is the object inserted).



11. Claims 5, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **De la Torre et al (5,957,913)** and further in view of **Hyodoh et al. (US 2003/0040772 A1)**.

Regarding claim 5, De la Torre discloses that the obturation elements (Figure 32, (392)) are made from a flexible and resilient material (Column 15, Line 40) and that the invention can be constructed of various different types of materials acceptable for use in surgical instruments. De la Torre fails to disclose that the obturation elements are made from a polymeric material.

However Hyodoh teaches that it is well known in the art to use polymeric materials, such as polyester, in surgical instruments (Paragraph [0032]; Paragraph [0042]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polymeric material for the obturation elements as taught by Hyodoh, since De la Torre stated that any material acceptable for use in surgical instruments can be used.

Regarding claim 16, De la Torre discloses an occlusive device but fails to disclose a removable sleeve surrounding the device.

However, Hyodoh teaches a removable sleeve surrounding the occlusive device in order to improve the insertion and delivery of the occlusive device (Paragraph [0230]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to surround the occlusive device of De la Torre with the sleeve as

taught by Hyodoh since such a modification would improve the insertion and delivery of the device.

Allowable Subject Matter

12. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Mialhe (WO 02/19926 A1), Kavteladze et al. (6,063,113), Yencho et al. (US 6,461,320 B1), Callister et al (US 2002/0029051 A1), Bash et al (WO 02/32320 A2), Pinchuk et al (EP 0864300 A1).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (570) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4148

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Erin Colello
February 25, 2008

/Terrell L Mckinnon/
Supervisory Patent Examiner, Art Unit 4148